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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,461	07/10/2001	Yuan-Tsong Chen	2984.1000-004	6796

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EXAMINER

MELLER, MICHAEL V

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 12/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/902,461

Applicant(s)

CHEN, YUAN-TSONG

Examiner

Michael V. Meller

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 and 11-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term, "regular interval" is vague and indefinite. What is a regular interval ? It could be anything. Interval to what ?

In claim 22, it is unclear if the composition comprises both the enzyme and the label. When applicant added the new limitation, the claim became indefinite as to whether the label was with the enzyme in the composition or not.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 102***

Claims 1-4, 9, 10 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Fuller et al. (ref. AV2) for the reasons of record and for the reasons which follow.

Applicant argues that Fuller do not teach administering the enzyme to an individual, but it is clear on page 908, right column, that they clearly teach to do it.

Applicant next argues that Fuller do not teach administration of the enzyme at a "regular interval". First of all the term is met since the enzyme is administered to cells. Treating any disease always requires a daily, or hourly treatment regime, thus the reference teaches the claimed invention.

Fuller clearly contemplates to treat glycogen storage disease type II patients with the enzyme, thus the claims are anticipated.

### ***Claim Rejections - 35 USC § 103***

Claims 1-7, 11-18 and 21 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fuller et al. (ref. AV2) for the reasons of record and for the reasons which follow.

Applicant presents the same arguments as above, thus the same rebuttal is offered.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuller et al. (ref. AV2) for the reasons of record and for the reasons which follow.

Applicant presents the same arguments as above, thus the same rebuttal is offered.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bijvoet et al. (ref. AR2) in view of Fuller et al. (ref. AV2) for the reasons of record and for the reasons which follow.

Applicant argues that the reference does not teach administration of the enzyme to an individual but it is clear from the reference that that is not the case. Bijvoet clearly administers the enzyme to an individual, namely mice, see abstract, page 1816, etc.

Applicant also argues that Bijvoet does not teach administration at a regular interval. Applicant is directed to the above discussion of Fuller.

Lastly, applicant argues that Bijvoet teaches away from the present invention, but it is clear in Bijvoet that eventhough they may have predicted high production costs using the enzyme produced from CHO cells, they state that potentially cheaper production is only under development. Also they clearly throughout the reference use the enzyme produced in CHO cells. So, while expensive, it still is desirable.

The teachings of Fuller are of record as well as the arguments and the above discussion of Fuller.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read 'M. Meller', followed by a horizontal line.

Michael V. Meller  
Examiner  
Art Unit 1654

MVM  
November 25, 2002